

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Confirmation No. 9373

Michael R. EMMERT-BUCK et al.

Application No.: 10/796,288

Art Unit: 3732

Filed: March 10, 2004

Examiner: Unassigned

Title: LIQUID TISSUE PREPARATION FROM HISTOPATHOLOGICALLY PROCESSED BIOLOGICAL SAMPLES, TISSUES AND CELLS

# INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56 and 37 CFR §1.97

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08A is a listing of documents known to applicants in order to comply with applicants' duty of disclosure pursuant to 37 C.F.R. §1.56 and §1.97. A copy of each of the listed documents are being submitted to comply with the provisions of 37 C.F.R. §1.97-1.99.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or is considered to be material to patentability as defined in 37 C.F.R. §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* prior art reference against the claims of the present application.

#### RELEVANCE STATEMENT

The relevance of the documents are described in the present specification.

U.S. Application No. 10/796,288

Inventor: Michael R. EMMERT-BUCK et al.

#### **TIMING/FEE**

The instant Information Disclosure Statement is being filed in compliance with 37 CFR §1.97(b) prior to the mailing date of the first official action, therefore, no fee is required in connection with its filing. However, the Commissioner is hereby authorized to charge any deficiency or to credit any overpayment to Deposit Account No. 08-1641.

Applicant respectfully requests that the listed documents be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08A be returned in accordance with M.P.E.P. §609.

Respectfully submitted,

Bv:

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Complete if Known **Application Number** 10/796,288 Filing Date March 10, 2004 First Named Inventor Marlene M. DARFLER et al. Group Art Unit 3732 Unassigned **Examiner Name** 40970-0002

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Substitute for form 1449A/PTO

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of T² Cite the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue xaminer No.1 Initials ' number(s), publisher, city and/or country where published. BANERJEE S.K. et al., "Microwave-Based DNA Extraction from Paraffin-Embedded Tissue for PCR A01 Amplification", Biotechniques, 1995, pp. 768-70, Vol. 18, No. 5 KRZYSZTOF BIELAWSKI et al., "The suitability of DNA extracted from formalin-fixed, paraffin-A02 embedded tissues for double differential polymerase chain reaction analysis", International Journal of Molecular Medicine, 2001, pp. 573-578, Vol. 8 SUSAN A. BROOKS et al., "Release and analysis of polypeptides and glycopolypeptides from A03 formalin-fixed, paraffin wax-embedded tissue", Histochemical Journal, 1998, pp. 609-615, Vol. 30 N.J. COOMBS et al., "Optimisation of DNA and RNA extraction from archival formalin-fixed tissue", A04 Nucleic Acids Research, 1999, pp. i-iii, Vol. 27, No. 16 M.V. DWEK et al., "Oligosaccharide Release from Frozen and Paraffin-Wax-Embedded Archival A05 Tissues", Analytical Biochemistry, 1996, pp. 8-14, Vol. 242 JOHN W. GILLESPIE et al., "Evaluation of Non-Formalin Tissue Fixation for Molecular Profiling A06 Studies", American Journal of Pathology, February 2002, pp. 449-457, Vol. 160, No. 2 KIMIMASA IKEDA et al., "Extraction and Analysis of Diagnostically Useful Proteins from Formalin-A07 fixed, Paraffin-embedded Tissue Sections", The Journal of Histochemistry & Cytochemistry, 1998, pp. 397-403, Vol. 46, No. 3 HIKARU IZAWA et al., "Analysis of cyclin D1 and CDK expression in colonic polyps containing neoplastic foci: A study of proteins extracted from paraffin sections", Oncology Reports, 2002, pp. **A08** 1313-1318, Vol. 9 BATIA KAPLAN et al.. "MICROEXTRACTION AND PURIFICATION TECHNIQUES APPLICABLE TO CHEMICAL CHARACTERIZATION OF AMYLOID PROTEINS IN MINUTE AMOUNTS OF A09 TISSUE", Methods in Enzymology, pp. 67-81, Vol. 309 B. KAPLAN et al., "Micropurification techniques in the analysis of amyloid proteins", J. Clin. Pathol, A10 2003, pp. 86-90, Vol. 56 ULRICH LEHMANN et al., "Quantitative Molecular Analysis of Laser-Microdissected Paraffin-A11 Embedded Human Tissues", Pathobiology, 2000, pp. 202-208, Vol. 68 ULRICH LEHMANN et al., "Real-Time PCR Analysis of DNA and RNA Extracted from Formalin-A12 Fixed and Paraffin-Embedded Biopsies", 2001, pp. 409-418, Vol. 25 F. LEWIS et al., "Unlocking the archive - gene expression in paraffin-embedded tissue", Journal of A13 Pathology, 2001, pp. 66-71, Vol. 195 NEIL MACINTYRE, "Unmasking antigens for immunohistochemistry", British Journal of Biomedical A14 Science, 2001, pp. 190-196, Vol. 58

Examiner	Date	
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	INITA!	OBA A TION	DIO		Application Number	10/796,288	
INFORMATION DISCLOSURE					Filing Date	March 10, 2004	
STATEMENT BY APPLICANT				PPLICANT	First Named Inventor	Marlene M. DARFLER et al.	
					Group Art Unit	3732	
	(use as many sheets as necessary)			necessary)	Examiner Name	Unassigned	
$\overline{\ }$	Sheet	2	of	2	Attorney Docket Number	40970-0002	

OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²		
	A15	CHARLES MURFF et al., "A Simple Experimental Model to Isolate Antigenic Epitopes Recognized by Antibodies", Bioscene, April 1998, pp. 11-15, Vol. 24, No. 1			
	A16	YUMIKO NITTA et al., "The Quality of DNA Recovered from the Archival Tissues of Atomic Bomb Survivors is Good Enough for the Single Nucleotide Polymorphism Analysis in Spite of the Decadelong Preservation in Formalin", J. Radiat. Res., 2002, pp. 65-75, Vol. 43			
	A17	W. ROY OVERTON et al., "Reversing the Effect of Formalin on the Binding of Propidium lodide to DNA", Cytometry, 1994, pp. 351-356, Vol. 16			
	A18	W. ROY OVERTON et al., "Method to Make Paraffin-Embedded Breast and Lymp Tissue Mimic Fresh Tissue in DNA Analysis", Cytometry (Communications in Clinical Cytometry), 1996, pp. 166-171, Vol. 26			
	A19	CLOUD P. PAWELETZ et al., "Reverse phase protein microarrays which capture disease progression show activation of pro-survival pathways at the cancer invasion front", Oncogene, 2001, pp. 1981-1989, Vol. 20			
	A20	ELIZABETH L. SCHUBERT et al., "Single Nucleotide Polymorphism Array Analysis of Flow-Sorted Epithelial Cells from Frozen Versus Fixed Tissues for Whole Genome Analysis of Allelic Loss in Breast Cancer", American Journal of Pathology, January 2002, pp. 73-79, Vol. 160, No. 1			
	A21	ERICA J. SIMEL et al., "Enhanced DNA Extraction and PCR Amplification of Mitochondrial Genes from Formalin-Fixed Museum Specimens", BioTechniqeus, March 1997, pp. 394-400, Vol. 22, No. 3			
	A22	SHAN-RONG SHI et al., "Antigen Retrieval Immunohistochemistry: Past, Present, and Future, The Journal of Histochemistry & Cytochemistry, 1997, pp. 327-343, Vol. 45, No. 3			
	A23	SHAN-RONG SHI et al., "Antigen Retrieval Techniques: Current Perspectives", The Journal of Histochemistry & Cytochemistry, 2001, pp. 931-937, Vol. 49, No. 8			
-	A24	SHAN-RONG SHI et al., "DNA Extraction from Archival Formalin-fixed, Paraffin-embedded Tissue Sections Based on the Antigen Retrieval Principle: Heating Under the Influence of pH", The Journal of Histochemistry & Cytochemistry, 2002, pp 1005-1011, Vol. 50, No. 8			
	A25	SHAN-RONG SHI et al., "Antigen Retrieval in Formalin-fixed, Paraffin-embedded Tissues: An Enhancement Method for Immunohistochemical Staining Based on Microwave Oven Heating of Tissue Sections", The Journal of Histochemistry & Cytochemistry, 1991, pp. 741-748, Vol. 39, No. 6			
	A26	SHAN-RONG SHI e al., "Antigen Retrieval Technique: A Novel Approach to Immunohistochemistry on Routinely Processed Tissue Sections", The Journal of Histochemistry & Cytochemistry, Cell Vision, 1995, pp 6-22, Vol. 2, No. 1			
	A27	SESHI R. SOMPURAM, Ph.D. et al., "A Molecular Mechanism of Formalin Fixation and Antigen Retrieval", Am J. Clin Pathol., 2004, pp 190-199, Vol. 121			
	A28	TAKEHIKO MIYAJI et al., "Frozen Protein Arrays: A new method for arraying and detecting recombinant and native tissue proteins," Proteomics 2002, 2, 1489-1493.			

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